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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS:	Klaus HERMANN	CONFIRMATION NO. 6825
SERIAL NO.:	09/993,176	GROUP ART UNIT: 3737
FILED:	November 19, 2001	EXAMINER: William C. Jung
TITLE:	**METHOD AND APPARATUS FOR CHARACTERIZING A LOCATION AT AN EXAMINATION SUBJECT**	

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Commissioner for Patents
P.O. Box 1450
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APPELLANT'S MAIN BRIEF ON APPEAL

S I R:

In accordance with the provisions of 37 C.F.R. §1.41.37, Appellant herewith submits his main brief in support of the appeal of the above-referenced application.

REAL PARTY IN INTEREST:

The real party in interest is the assignee of the present application, Siemens Aktiengesellschaft, a German corporation.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals and no related interferences.

STATUS OF CLAIMS:

Claims 1-38 are presented for review in this appeal, all of which were finally rejected in the Office Action dated November 4, 2004. The application was filed with all of these claims as the original claims. No claim was cancelled or added during prosecution.

STATUS OF AMENDMENTS:

This Appeal Brief is accompanied by Amendment "B" that is solely for the purpose of correcting an obvious typographical error in claim 1. Since Amendment "B" is being filed simultaneously with this Appeal Brief, Amendment "B" has not yet been entered. In view of the fact that Amendment "B" is solely editorial in nature, and does nothing more than correct a typographical error in claim 1, Appellant assumes that Amendment "B" will be entered, and therefore claim 1 in the Appendix attached hereto embodies the correction of the typographical error.

SUMMARY OF THE CLAIMED SUBJECT MATTER:

Figure 1 schematically shows a side view of a C-arm X-ray apparatus 1 constructed and operating according to the claims on appeal. The C-arm X-ray apparatus 1 has an apparatus carriage 3 movable on wheels 2. The C-arm X-ray apparatus 1 has a lifting mechanism 4 with a column 5 schematically indicated in Figure 1. A holder 6 is arranged at the column 5, a support 7 for a C-arm 8 being in turn arranged at the holder 6. The C-arm 8 carries an X-ray source 9 and an X-ray detector 10 that are arranged opposite one another at the C-arm 8 so that a central ray ZS of an X-ray beam emanating from the X-ray source 9 strikes the detector surface of the radiation detector 10 approximately centrally. (p. 5, l. 9-16)

In a known way, the support 7 is seated at the holder 6 so as to be rotatable around a common axis A of the holder 6 and the support 7 (see double arrow 'a', angulation) and can be displaced in the direction of the axis A (see double arrow 'b'). Along its circumference, the C-arm 8 is seated to be displaceable in the direction of the double arrow 'o' at the support 7 relative to the support 7 (orbital motion). (p. 5, l. 17-21)

The C-arm 8, which is connected to the column 5 of the lifting mechanism 4 via the support 7 and the holder 6, is vertically adjustable relative to the device carriage 3. (p. 6, l. 1-2)

A patient P schematically shown in Figure 1 lies on a table T that is likewise only schematically indicated and is transparent for X-radiation, and is vertically adjustable with a lifting mechanism (not shown). As a result of the aforementioned adjustment possibilities of the C-arm X-ray apparatus 1 and the table T, the patient P can be radiologically examined a large variety of ways, whereby the X-rays with the central ray ZS emanating from the X-ray source 9 penetrating the patient P and strikes the radiation detector 10. (p. .6, l. 3-9)

The C-arm X-ray apparatus 1 is particularly suitable for producing a volume dataset of body parts of the patient P. (p. 6, l. 10-11) In the exemplary embodiment, a computer 11 is arranged in the device carriage 3, the computer 11 being connected to the radiation detector 10 (in a way that is not shown) and reconstructing a volume dataset of the body part to be displayed in a known way from a series of 2d projections acquired with the X-ray source 9 and the radiation detector 10. (p. 6, l. 11-15) These images are acquired with an adjustment of the C-arm around a body part of the patient P to be displayed in an image. (p. 6, l. 15-17) The C-arm is adjusted by about 190° along its circumference in the direction of the double arrow 'o' relative to the support 7 or relative to the angulation axis A, with approximately 50 through 100 2D projections being acquired during the adjustment. In the present exemplary embodiment, the computer 11 controls the adjustment of the C-arm 8 with an electrical drive 12 arranged in the support 7 or with an electrical

drive 13 arranged in the holder 6. (p. 6, l. 17-22) The computer 11 is connected to the electrical drives 12 and 13 in a way that has not been shown. (p. 6, l. 22-23)

In order to reconstruct the volume dataset from the series of 2D projections, respective distance sensors 14 and 15 are integrated in the electrical drives 12 and 13. (p. 7, l. 1-2) The sensors 14 and 15 allocate a position of the C-arm 8 relative to the body part to be displayed for each of the 2D projections of the body parts to be registered. (p. 7, l. 3-4) Projection geometries that are required for the reconstruction are determined from the positions. (p. 7, l. 5-6)

In the exemplary embodiment, the patient P has a fracture F at the left shin bone SB that is shown excerpted and schematically in Figure 2 and that is to be fixed with a nail N. (p. 7, l. 7-9) In order to plan the position of the nail N, an operator (not shown) uses the C-arm X-ray apparatus 1 to generate a volume dataset of the region of interest of the left shin bone SB. (p. 7, l. 9-11) Using known methods, for example the MPR (multi-planar reformation) method, the computer 11 produces 2D images of the left shin bone SB in a first operating mode and 3D images of the left shin bone SB in a second operating mode, these being displayable on a monitor 20 that is connected to the computer 11 with an electrical line 21. (p. 7, l. 11-15)

As an example, Figure 3 shows an image SB' of the broken left shin bone SB displayed on the monitor 20. In the exemplary embodiment, the image SB' is a 2D image, and the picture of the fracture F of the left shin bone SB is referenced F' in Figure 3. (p. 7, l. 11-15)

In the exemplary embodiment with a computer mouse 22 that is connected to the computer 11 with an electrical line, an arrow-shaped marking 24 that

corresponds to the future position and alignment of the nail N is set in the image SB'. (p. 7, l. 20-22)

After setting the marking 24, the computer 11 assigns a position in the patient to the marking 24 based on the volume dataset, the nail N to be arranged at the shin bone SB of the patient P at said position. (p. 7, l. 23 – p. 8, l. 17) Subsequently, the computer 11 adjusts the C-arm 8 with the distance sensors 14 and 15 and the electrical drives 12 and 13 so that a laser beam 26 proceeding from a laser light sighting device 25 arranged at the C-arm 8 characterizes a location 27 at the patient P at which the nail N for fixing the shin bone SB can be introduced so that the nail N assumes the position that corresponds to the marking 24 set in the image SB'. (p. 8, l. 1-6) The laser beam also indicates the angle at which the nail N should be introduced. (p. 8, l. 6-7)

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

The following issues are presented for review in the present appeal:

(1) Whether the subject matter of claims 1-8, 10-12, 16-27, 29-31 and 35 – 38 is anticipated under 35 U.S.C. §102(b) by United States Patent No. 6,149,592 (Yanof et al);

(2) Whether the subject matter of claims 9 and 28 would have been obvious to a person of ordinary skill in the field of computed tomography under the provisions of 35 U.S.C. §103(a), based on the teachings of Yanof et al, in view of the teachings of United States Patent No. 5,354,314 (Hardy et al); and

(3) Whether the subject matter of claims 13-15 and 32-34 would have been obvious to a person of ordinary skill in the field of computed tomography under

the provisions of 35 U.S.C. §103(a) based on the teachings of Yanof et al, in view of the teachings of United States Patent No. 6,096,049 (McNeirney et al).

ARGUMENT:

REJECTION OF CLAIMS 1-8, 10-12, 16-27, 29-31 and 35-38 AS BEING ANTICIPATED BY YANOF ET AL

The method and apparatus disclosed and claimed in the present application are for the purpose of aiding a physician during an interventional procedure to position a surgical item that is to be inserted into the patient to assist in the setting or healing of a fracture. The item may be, for example, a pin, a screw or a Kirschner wire. In the inventive method and apparatus, a volume dataset is acquired with an imaging modality, such as an x-ray imaging system, and an image of the subject is produced from this volume dataset. This image is displayed at a monitor and the position in the patient of the item to be inserted is marked in the displayed image. Using the marking in the displayed image, an association can be calculated between the marking in the image and corresponding physical (real) location at the patient. A location characterizing unit, such as a unit that generates a light beam, in one example, is then adjusted in position so that it characterizes a physical location at the patient corresponding to the marked location, so that the position can insert the item at the designated location at the subject.

Thus, the location that is characterized by the location characterizing unit is a real, physical location at the patient on the operating table, and is not a location that is characterized in an image or some other representation of the subject.

The Yanof et al reference, by contrast, discloses a method wherein the position of a minimally-invasive surgical instrument, that is inserted into a patient, is

mixed into an image that is acquired before the surgical procedure. This reference does not at all concern producing any kind of location indicator in, at or on the actual subject on the operating table.

Each of independent claims 1 and 20 makes clear that the characterization of the location at the subject means a physical characterization that is visible at the subject. This precludes claims 1 and 20 from reading on a device such as disclosed in the Yanof et al reference, wherein only indications in a video image are involved.

The Yanof et al reference therefore does not disclose all of the method steps of independent claim 1 nor all of the elements of independent claim 20, and therefore does not anticipate either of those claims, nor any of the claims respectively depending therefrom.

In the final rejection, in response to the aforementioned arguments that were made during prosecution, the Examiner stated that the Yanof et al reference explicitly states that the location of a surgical tool is guided to a target location by inserting a biopsy needle into a patient while the imaging device (CT or fluoroscope) provides feedback to generate the position of the surgical tool relative to the target location.

In response, Appellant acknowledges that this is an accurate statement of the teachings of the Yanof et al reference, but Appellant submits it does not respond to Appellant's arguments above, nor do those teachings correspond to the language of independent claims 1 and 20. As summarized at column 2, lines 24-31 of the Yanof et al reference, the teachings of that reference explicitly involve display of a representation of the surgical instrument only in the displayed image of the examination subject:

> "During the surgical procedure, real time images of the region of interest are generated, which real time images include an inserted portion of a surgical instrument. Coordinate positions of the surgical instrument are transformed into corresponding coordinates of the planning image. An image representation of the surgical instrument at corresponding coordinates of the planning image is generated."

The manner by which the coordinates of the surgical instrument are determined (using a mechanical arm assembly 64) is explained in detail in the Yanof reference at column 4, lines 26-47, and the manner by which the displayed representation of the instrument is indicated with the correct position in the displayed image of the region of interest is described at column 4, lines 48-64.

Moreover, in the paragraph bridging columns 6 and 7 of the Yanof et al reference, it is explicitly stated that the x-ray beam of the fluoroscopic device has a center line that can be aligned with a target in the patient. It is explicitly stated that the surgical instrument is positioned on and inserted along the center line *while watching the volume display* in three-dimensional space or the fluoroscopic display in two-dimensional space (emphasis added). The next sentence (column 7, lines 4-7) explicitly states that because the fluoroscopic display is generated during the surgical procedure, the instrument is *displayed* in the fluoroscopic image (emphasis added).

All of these explicit teachings in the Yanof et al reference make clear that the only indication of the surgical instrument that takes place in the Yanof et al reference is in the displayed image. There is no teachings in the Yanof et al reference corresponding to the language in method step (d) of claim 1, requiring that a location be characterized *physically at the subject*, at a location *that is visible at the subject.*

Similarly, there is no teaching of a location characterizing unit in the Yanof et al reference as set forth in claim 20, which interacts with the marking arrangement to characterize, *physically at the subject,* a location at the subject, *that is visible at the subject*, substantially corresponding to the location represented in the image that is identified by the mark that is set by the marking arrangement. Therefore, as noted by the Examiner, it is true that in the Yanof et al reference the surgeon is provided with feedback to allow the surgeon to guide a medical instrument within the examination subject, but in the Yanof et al reference this feedback is generated exclusively by a displayed representation of the surgical instrument in the displayed image of the examination subject. There is no physical, visible marking on the examination subject himself or herself that is generated in the Yanof et al reference.

REJECTION OF CLAIMS 9 and 28 AS BEING OBVIOUS IN VIEW OF YANOF ET AL AND HARDY ET AL

The Examiner stated the Yanof et al reference inherently includes a computer input peripheral device, but does not disclose inputting the aforementioned marker via such an input peripheral device. The Examiner relied on the Hardy et al reference as disclosing the use of a touch screen as an input device when using an imaging device such as a computed tomography apparatus. Appellant does not have a significant disagreement that the Hardy et al reference provides such teachings, but for the reasons discussed above, since the Yanof et al reference does not disclose or suggest all of the elements of independent claims 1 and 20, from which claims 9 and 28 respectively depend, Appellant submits that even if the Yanof et al reference were modified in view of the teachings of Hardy et al, the subject matter of claims 9 and 28 still would not result.

Claims 9 and 28, therefore, would not have been obvious to a person of ordinary skill in the field of computed tomography based on the teachings of Yanof et al and Hardy et al.

REJECTION OF CLAIMS 13-15 and 32-34 AS BEING OBVIOUS OVER YANOF ET AL AND MCNEIRNEY ET AL

The Examiner relied on the McNierney et al reference as teaching optical guidance of a medical device or an imaging device, wherein a light beam such as a laser is used to indicate the point of interest for the medical imaging device. Appellant respectfully submits this is a vast over-generalization of the teachings of McNeirney et al. The McNeirney et al reference is strictly directed to a handheld surgical instrument, wherein a laser beam is generated. The surgical instrument has a pointed end that is intended to puncture the skin of a patient. The laser beam proceeds in alignment with this point, and thus allows the physician to "follow" the laser beam as the medical instrument is moved closer and closer to the patient. This is solely to provide a visible aid to the physician, however, and there is no automatic or feedback-controlled guidance system disclosed in the McNierney et al reference that makes use of this laser beam.

The Yanof et al reference, because it is not intended to interact with a mark of any type that is physically present on the patient, does not include any arrangement for picking up or detecting a light beam, such as the laser that is employed in the handheld instrument disclosed in McNierney et al. Thus there is no way, in a combination of the teachings of Yanof et al and McNeirney et al, for any type of feedback-controlled or automated guidance of the medical instrument to occur, since for such guidance to occur it would be necessary first to be able to detect the laser

beam. Independent claims 1 and 20, from which claims 13-15 and 32-34 respectively depend, each require that a location be marked in an image of the patient, and then state that the location characterizing unit characterizes a location, physically at the subject, that is visible at the subject, *based on the mark in the image.* This clearly requires a capability of correlating the location characterizing unit with the mark that is entered into the image. Although the laser beam in the McNeirney et al reference will produce a laser beam point on the skin of the subject, in the McNeirney et al reference this is solely for the purpose of providing a visual aid to the surgeon for manipulating the hand-held instrument, and in the Yanof et al instrument there is no capability of correlating such a laser point with the displayed image of the instrument that is included in the displayed image of the examination subject. Visual indicators on the exterior of the patient in the Yanof et al reference, in whatever form, play no role whatsoever in the manipulation of the surgical instrument, which ensues exclusively by means of the displayed image.

Therefore, even if the Yanof et al reference were modified in accordance with the teachings of McNeirney et al, the subject matter of claims 13-15 and 32-34 still would not result. Claims 13-15 and 32-34, therefore, would not have been obvious to a person of ordinary skill in the field of computed tomography based on the teachings of Yanof et al and McNeirney et al.

CONCLUSION:

For the foregoing reasons, Appellant respectfully submits the Examiner is in error in law and in fact in rejecting claims 1-38 based on the above-discussed references. Reversal of those rejections are therefore proper, and the same is respectfully requested.

This Appeal Brief is accompanied by a check for the requisite fee in the amount of $500.00.

Submitted by,

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CERTIFICATE OF MAILING

I hereby certify that an original and two copies of this correspondence are being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on April 4, 2005.

Steven H. Noll

STEVEN H. NOLL

APPENDIX "A"

1. A method for characterizing a location at a subject, comprising the steps of:

(a) generating a volume dataset of a subject;

(b) generating an image from said volume dataset;

(c) marking a location in said image with a mark; and

(d) characterizing, physically at the subject, a location that is visible at the subject, with a location characterizing unit and, based on the mark in said image, adjusting said location characterizing unit relative to said subject so that said location characterizing unit characterizes said location physically at said subject substantially corresponding to the location in the image identified by said mark.

2. A method as claimed in claim 1 wherein step (a) comprises generating said volume dataset with an X-ray system.

3. A method as claimed in claim 2 comprising moving said X-ray system with at least one drive to generate said volume dataset.

4. A method as claimed in claim 3 comprising moving said X-ray system with at least one electric motor, as said drive, to generate said volume dataset.

5. A method as claimed in claim 3 comprising automatically moving said X-ray system with at least one drive to generate said volume dataset.

6. A method as claimed in claim 1 wherein step (b) comprises generating said image from said volume dataset using a computer, and wherein step (a) comprises generating said volume dataset using said computer.

7. A method as claimed in claim 1 wherein step (b) comprises selecting said image that is generated from the group consisting of two-dimensional images three-dimensional images.

8. A method as claimed in claim 1 comprising the additional step of displaying said image on a viewing device.

9. A method as claimed in claim 1 wherein step (c) comprising marking said location in said image with a marking device selected from the group consisting of a computer mouse, a track ball, a joystick, a light pen, and a touch screen.

10. A method as claimed in claim 1 wherein step (d) comprises adjusting said location characterizing unit with a drive.

11. A method as claimed in claim 10 comprising adjusting said location characterizing unit with an electric motor, as said drive.

12. A method as claimed in claim 10 comprising using said drive, automatically aligning the location characterized by said location characterizing unit with said mark.

13. A method as claimed in claim 1 wherein step (d) comprises characterizing said location at said subject with an optical sighting device, as said location characterizing unit.

14. A method as claimed in claim 13 comprising emitting an optical beam from said optical sighting device to characterize said location at said subject.

15. A method as claimed in claim 14 comprising emitting a laser beam from said optical sighting device to characterize said location.

16. A method as claimed in claim 1 wherein step (a) comprises generating said volume dataset with a C-arm X-ray imaging system.

17. A method as claimed in claim 16 comprising moving said C-arm X-ray imaging system with respect to at least one of an angulation axis and an orbital axis to generate said volume dataset.

18. A method as claimed in claim 16 comprising mounting said location characterizing unit at said C-arm X-ray imaging system.

19. A method as claimed in claim 18 wherein step (d) comprises moving said C-arm X-ray imaging system, with said location characterizing unit mounted thereon, to adjust said location characterizing unit.

20. An apparatus allowing a location at an subject to be characterized, comprising:

an arrangement for generating a volume dataset of a subject;

an arrangement for generating an image from said volume dataset;

a marking arrangement for setting a mark in said image which identifies a location in said subject represented in said image; and

a location characterizing unit which interacts with said marking arrangement to characterize, physically at said subject, a location at said subject, that is visible at said subject, substantially corresponding to the location represented in said image identified by said mark.

21. An apparatus as claimed in claim 20 wherein said arrangement for generating a volume dataset is an X-ray system.

22. An apparatus as claimed in claim 20 wherein said arrangement for generating a volume dataset includes data-generating components, and at least one drive for moving said data-generating components.

23. An apparatus as claimed in claim 22 wherein said drive is an electric motor.

24. An apparatus as claimed in claim 22 wherein said data-generating components are automatically moved by said drive.

25. An apparatus as claimed in claim 20 wherein said arrangement for generating an image from the volume dataset is a computer, and wherein said arrangement for generating a volume dataset also comprises said computer.

26. An apparatus as claimed in claim 20 wherein said arrangement for generating an image from said volume dataset generates said image from the group consisting of two-dimensional images and three-dimensional images.

27. An apparatus as claimed in claim 20 wherein said arrangement for generating an image from the volume dataset includes a viewing device on which said image is displayed.

28. An apparatus as claimed in claim 20 wherein said marking arrangement comprises a marking device selected from the group consisting of a computer mouse, a track ball, a joystick, a light pen, and a touch screen.

29. An apparatus as claimed in claim 20 comprising a drive connected to said location characterizing unit for moving said location characterizing unit.

30. An apparatus as claimed in claim 29 wherein said drive is an electric motor.

31. An apparatus as claimed in claim 29 wherein said drive automatically aligns said location characterizing unit to characterize said location substantially corresponding to the location marked in the image.

32. An apparatus as claimed in claim 20 wherein said arrangement for characterizing a location is an optical sighting device.

33. An apparatus as claimed in claim 32 wherein said optical sighting device emits an optical beam to characterize said location at said subject.

34. An apparatus as claimed in claim 33 wherein said optical sighting device is a lower sighting device which emits a laser beam.

35. An apparatus as claimed in claim 20 wherein said arrangement for generating a volume dataset comprises data-generating components mounted on a C-arm.

36. An apparatus as claimed in claim 35 wherein said C-arm is movable relative to at least one of an angulation axis and an orbital axis to generate said volume dataset.

37. An apparatus as claimed in claim 35 wherein said location characterizing unit is mounted at said C-arm.

38. An apparatus as claimed in claim 37 wherein said C-arm is automatically moved, together with said location characterizing unit mounted thereon, to adjust said location characterizing unit.

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